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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,870	10/31/2003	Lola M. Reid	320727.51001	9017
27160 7590 01/10/2007 PATENT ADMINISTRATOR KATTEN MUCHIN ROSENMAN LLP 1025 THOMAS JEFFERSON STREET, N.W. EAST LOBBY: SUITE 700 WASHINGTON, DC 20007-5201			EXAMINER BOWERS, NATHAN ANDREW	
			ART UNIT	PAPER NUMBER
			1744	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/10/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/697,870

Applicant(s)

REID ET AL.

Examiner

Nathan A. Bowers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 8 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6, 7 and 10-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>072105</u>                                                    | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 1-5, 8 and 9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 07 November 2006.

Applicant's election with traverse of Group III, claims 6, 7 and 10-14 in the reply filed on 07 November 2006 is acknowledged. The traversal is on the ground(s) that there is no undue burden to examine the claims together. This is not found persuasive because the claims are drawn to different subclasses, and therefore require different searches.

The requirement is still deemed proper and is therefore made FINAL.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1) Claims 6, 7 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by MacDonald "Bioartificial livers."

With respect to claims 6 and 13, MacDonald discloses a device for maintaining viable eukaryotic cells. The device comprises a woven fabric forming an annular compartment having an annular space, and at least two additional compartments adjacent and coaxial to the annular space. Each compartment is fully capable of containing a liquid. See the "Coaxial-Type Hollow-Fiber Bioreactors" section and Figure 21.7 on pages 276 and 277. Since MacDonald teaches that air mixtures flow through the intracapillary space, an integral aeration supply must be provided.

With respect to claim 7, MacDonald discloses the apparatus of claim 6 wherein the woven fabric comprises a woven polyester. Specifically, MacDonald discloses the use of cellulose acetate.

2) Claims 6, 7 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Martinez (US 6582955).

With respect to claims 6 and 13, Martinez discloses a device for maintaining viable eukaryotic cells comprising a woven fabric (Figure 5:18) forming an annular compartment having an annular space. At least two additional compartments adjacent and coaxial to the annular space are provided. Each compartment is fully capable of holding a liquid. This is described in column 2, lines 53-67 and column 4, line 66 to column 5, line 65. Column 4, lines 1-7 indicate that oxygen is delivered to fluid moving through the annular space. Therefore, an aeration supply must be provided.

With respect to claim 7, Martinez discloses the apparatus in claim 6 wherein the woven fabric comprises a woven polyester. Column 3, lines 52-61 suggests the use of mixed ester cellulose hollow fibers.

With respect to claim 10, Martinez discloses a bioreactor comprising a housing (Figure 3:17) that includes an array of a plurality of modules of textile vasculatures. Each module comprises a plurality of coaxial textile vasculatures and a plurality of compartments. A first compartment is defined by the inner side of the innermost textile vasculature (Figure 5:19), and a second compartment is defined by a respective annular space formed by the outer textile vasculature (Figure 5:18). An outermost compartment (Figure 5:15) is defined by a space within the inner side of the housing which is not occupied by the plurality of modules. This design is described in column 2, lines 53-67 and column 4, line 66 to column 5, line 65. Column 4, lines 1-7 indicate that fluids are moved through the first compartment in order to deliver oxygen to fluid moving through the second compartment. Accordingly, Martinez discloses a gas introduction means (Figure 4:24) integral to the housing and a gas expiration means (Figure 4:25) integral to the housing. It is understood that Martinez teaches in column 5, lines 10-21 that these inlets and outlets are intended for the facilitating the flow of a hemodialysis fluid, rather than a gas. However, since Martinez does disclose a desire to provide an oxygen supply to the annular space using the first compartment, the disclosed introduction and expiration means are considered to be fully capable of delivering and withdrawing a gas to and from the first compartment.

With respect to claim 11, Martinez discloses the apparatus in claim 10 wherein the woven fabric comprises a woven polyester. Column 3, lines 52-61 suggests the use of mixed ester cellulose hollow fibers.

With respect to claim 14, Martinez discloses the apparatus in claim 10 wherein viable cells are introduced to the second compartment formed between the annular woven fibers. A nutrient medium is passed through the first compartment in order to accommodate cell growth. This is described in claim 1 of the Martinez reference. Martinez discloses in the "Background" section that it is well known in the art to utilize a parallel flow of cells and nutrients in coaxial bioreactors.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3) Claims 6, 7 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martinez (US 6582955) in view of Nunez (US 6840958) and/or Kapadia (US 4816028).

Martinez discloses the apparatuses set forth in claims 6, 7 and 13 as previously described in the rejections above. It is believed that Martinez discloses that the annular compartments are formed by a woven fabric. However, if it is determined that Martinez does not teach that the fabric is woven, then Martinez fails to anticipate the claimed devices.

Nunez and Kapadia both disclose the use of woven polyester vasculatures.

Martinez, Nunez and Kapadia are analogous art because they are from the same field of endeavor regarding textile vasculatures.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to ensure that the vasculatures disclosed by Martinez were of a woven polyester.

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Woven polyester vasculatures are considered to be well known in the art, as evidenced by Nunez and Kapadia. Woven grafts are beneficial because they are generally characterized by a uniform surface resulting in smoother blood flow. Woven materials can be created at various porosities in order to facilitate the diffusion of desired compounds.

4) Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martinez (US 6582955) in view of Ghezzi (US 5194157).

Martinez discloses a bioreactor comprising a housing (Figure 3:17) that includes an array of a plurality of modules of textile vasculatures. Each module comprises a plurality of coaxial textile vasculatures and a plurality of compartments. A first compartment is defined by the inner side of the innermost textile vasculature (Figure 5:19), and a second compartment is defined by a respective annular space formed by the outer textile vasculature (Figure 5:18). An outermost compartment (Figure 5:15) is defined by a space within the inner side of the housing which is not occupied by the plurality of modules. This design is described in column 2, lines 53-67 and column 4, line 66 to column 5, line 65. Column 4, lines 1-7 indicate that fluids are moved through the first compartment in order to deliver oxygen to fluid moving through the second compartment. Accordingly, Martinez discloses an introduction means (Figure 4:24) integral to the housing and an expiration means (Figure 4:25) integral to the housing, each of which are fully capable of accommodating the movement of gases through the



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bioreactor. Martinez, however, does not expressly indicate the presence of multiple bioreactors that are serially linked.

Ghezzi discloses a blood purifying system in which a plurality of bioreactors are serially linked. Specifically, Ghezzi indicates that blood moves sequentially from a hemofiltration element (Figure 1:2) to a hemodialysis element (Figure 1:3). This is described in column 2, line 61 to column 3, line 30. Blood is processed in both elements through the exchange of fluids across permeable membranes.

Martinez and Ghezzi are analogous art because they are from the same field of endeavor regarding blood processing bioreactors.

At the time of the invention, it would have been obvious to link the bioreactors disclosed by Martinez in a series in order to more thoroughly process the fluids moving through the units. Ghezzi teaches that arrangements that utilize serially linked bioreactors are beneficial because they allow each individual bioreactor unit to specialize in a specific operation. By connecting a plurality of Martinez's bioreactors in succession, one would have been able to ensure that blood is fully processed before it is returned to a patient.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

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F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 6, 7 and 10-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 23 and 29 of copending Application No. 11/226351. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of Application No. 11/226351 are generic to the claims of the instant application. Application No. 11/226351 includes all of the limitations set forth in the instant invention, however does not specifically disclose the use of vasculatures. Application No. 11/226351 does include limitations in the claims regarding the use of hollow fibers containing liver cells.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### **Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Robinson (US 5015585) reference discloses the state of the art regarding coaxial bioreactors.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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